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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
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HOWERY SIMON ARNOLD AND WHITE, LLP  
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EXAMINER	
SNEDDEN, SHERIDAN	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/820,053

Applicant(s)

OWEN, DONALD R.

Examiner

Sheridan K Snedden

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 01 July 2003 and 04 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-7 and 53-64 is/are pending in the application.
- 4a) Of the above claim(s) 53,54,59 and 61-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,55-58 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 8, 12 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment of claims 1, 6 and 7; cancellation of claims 8-52; and addition of new claims 53-63 in Paper No. 11, filed 4 April 2003 is acknowledged. Applicant's addition of new claim 64 in Paper No. 14, filed 19 June 2003 is acknowledged.

2. Applicant's election of invention I, claims 1-7 is acknowledged. Applicant's additional election of SEQ ID NO: 43 is acknowledged. Claims 53, 54, 59, and 61-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **with** traverse in Paper No. 11 and 15.

Applicant argues that the peptides of recited in the claims describe a class of peptides having particular length and sequence properties. This argument is considered but not found to be persuasive because a thorough examination of all the claims in the instant application requires individual searches on each of the sequences against all the databases at the PTO. The peptides differ in length and amino acid sequence in such as way that one peptide would not render obvious every peptide of the recited claims. Because these inventions are distinct for the reasons given above (see also Paper No: 9) and the search required for SEQ ID NO: 43 is not required for any one of SEQ ID NO: 11-29, for example, restriction for examination purposes as indicated is proper.

3. Claims 1-7, 55-58 and 60 are under examination.

### ***Claim Objections***

Claims 5, 6, 7 and 60 are objected to as they recite non-elected subject matter.

Applicant's election in Paper # 15 was to the peptide of SEQ ID NO: 43.

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***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 55-58 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The phrase "at least about" in claim 1 renders the claim indefinite. The specification and prior art do not provide a standard for ascertaining what range is specifically covered, and one of ordinary skill in the art could not reasonably define the invention. Is 70% about 80%? The prior art teaches peptides containing about 80% Phe, Leu, Ala, and Lys, and as such the range recited in the claim is indefinite. See also same issue in claim 6. Claims 1-7, 55-58 and 60 are indefinite as they depend from claim 1 and do not clarify the ambiguity.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claims 1-3, 6, 55-57 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Julian *et al.* (US 5,717,064). Julian *et al.* teach a peptide having an amino acid sequence of 23 in length (considered about 15, about 20 or about 22 amino acids, regarding claims 1,2, and 55 - 57); is 100% phenylalanine, leucine, alanine, and lysine; and is 72.7% identical to SEQ ID NO: 43 (80% identical from amino acids 1-15). Thus, the reference anticipates the claimed invention.

8. Claims 1-4, 55-58 and 60 rejected under 35 U.S.C. 102(e) as being anticipated by Alibhai *et al.* (WO 01/49834). Alibhai *et al.* teach a peptide having an amino acid sequence of Ala-Ala-Leu-Ile-Ala-Phe-Ala-Lys-Leu-Leu (SEQ ID NO: 234). This peptide is 10 residues in length (considered about 15 amino acids, regarding claim 56 and 58) and is 100% phenylalanine, leucine, alanine, and lysine. Thus, the reference anticipates the claimed invention.

9. Claims 1-4, 55 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Nordstedt *et al.* (US Patent 6,331,440). Nordstedt *et al.* teach a peptide having an amino acid sequence of Lys-Leu-Val-Ala-Phe (KLVAF, see claim 5). This peptide is 5 residues in length and is 80% phenylalanine, leucine, alanine, and lysine. Thus, the reference anticipates the claimed invention.

10. Claims 1-3, 55-58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Bessalle *et al.* (IDS C1). Bessalle *et al.* teach a peptide having an amino acid sequence of 17 residues in length (considered about 15, about 20 or about 22 amino acids, regarding claims 1,2,

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and 55-57), and is 94% phenylalanine, leucine, alanine, and lysine. Thus, the reference anticipates the claimed invention.

*Conclusion*

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1800

SKS  
September 8, 2003

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